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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,159	01/20/2004	Biten K. Kathrani	END-5255	2562
27777 7590 02/21/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
EXAMINER STIGELL, THEODORE J				
ART UNIT		PAPER NUMBER		
3763				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/761,159

**Applicant(s)**

KATHRANI ET AL.

**Examiner**

THEODORE J. STIGELL

**Art Unit**

3763

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 10-11, 15-16, 18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burney et al. (5,800,389). Burney discloses a medical device (10) comprising a first elongate member (20), a second elongate member (11) having an open proximal end and an open distal end (13), wherein the first member is releasably attachable to the second member to provide a continuous fluid passageway, wherein the outer diameter of the first elongate member is greater than the internal diameter of the second member, and wherein the distal end of the first member is positioned intermediate the proximal and distal ends of the second member upon attachment of the two members (see figure 4, element 13 extends past distal end 21), wherein the first member has a closed, pointed, non-bifurcated distal tip (30), wherein the first member comprises a relatively rigid body portion (40) and a relatively flexible distal end portion (20), wherein the first member can be considered a hollow cannula extension, and the second member can be considered a cannula, wherein the first member comprises at least one side hole (24) and a sleeve (41), and wherein at least one of the first and

second members comprise a non-circular cross section at least partially somewhere along the length of the device.

Claims 1-2, 4-10, 13, 15-16, 18-22, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Liegner (4,803,999). Liegner discloses a medical device (10) for providing access to an internal space in a patient, the device comprising a first elongate member (12) having a proximal end, a distal end, an outer diameter, and an internal lumen, a second elongate member (14) having an open proximal end, an open distal end, and an internal lumen having an internal diameter and providing a passageway extending therethrough, wherein the first member is releasably attachable to the second member to provide a generally continuous fluid passageway, wherein the outer diameter of the first elongate member is greater than the internal diameter of the internal lumen of the second elongate member, and such that the distal end of the first member is positioned intermediate the proximal and distal ends of the second member upon attachment of the second member to the first member (see figure 2), wherein the first member has an open, pointed, non-bifurcated distal tip (15), further comprising a cap (18) releasably attachable to either member, wherein the second member has a beveled distal end (27), and further comprising a sleeve (30).

Claims 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama (3,896,810). Akiyama discloses an assembly comprising a vacuum device (28, 32) for providing an operative space within a patient, and a multi-component device for providing access from the vacuum to a point within the patient, the multi-component device comprising a detachable first (15) and second (10) members, the first member

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for providing a first portion of a passageway, and the second member for providing a second portion of a passageway.

In regards to claim 27, Akiyama discloses a medical device comprising a cannula (10) having an outside surface, an open proximal end, an open distal end, an internal lumen extending from the proximal end to the distal end, and a cannula extension (15) having an open proximal end, a distal end, and an internal lumen, wherein the distal end of the cannula extension is sized to be received within the proximal end of the cannula, wherein the cannula extension is releasably attachable to a proximal portion of the cannula such that the distal end of the cannula extension is positioned within the internal lumen of the cannula a predetermined distance from the open distal end of the cannula (functional limitation), and wherein the distal end of the cannula extension extends less than halfway into the internal lumen of the cannula (functional limitation).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (5,800,389) or Liegner (4,803,999). Burney et al. and Liegner disclose all of the limitations recited in the independent claims but fail to disclose the limitations recited in the claims 12 and 14. However, the applicant has failed to disclose that these limitations solve any problem or are for any particular purpose. Therefore, these limitations are deemed to be matters of design choice that fail to patentably distinguish over the prior art.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (5,800,389) or Liegner (4,803,999). Burney and Liegner disclose the claimed invention except for using a transparent wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use transparent material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (5,800,389) or Liegner (4,803,999) in view of Sommerich (6,916,310). Burney et al. and Liegner disclose all of the limitations recited in the independent claims but fail to disclose the use of a medicinal coating on the sleeve. Sommerich teaches a medical sleeve that comprises a sealing surface and is adapted to provide a substantially airtight seal between the patient and an inserted tube. (See Figure 2) The

sleeve is coated with an antibacterial substance (See Claim 25). To one of ordinary skill in the art at the time of the invention, it would have been obvious to modify the disclosure of Burney et al. and Liegner with the teachings of Sommerich to provide a sleeve with a medicinal coating to reduce the risk of infection.

***Response to Arguments***

Applicant's arguments with respect to claims 1-24 and 26-27 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

